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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,722	08/27/2001	Ronald A. Schachar	PRES06-00217	5803

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Docket Clerk
P.O. Drawer 800889
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EXAMINER

WILLSE, DAVID H

ART UNIT PAPER NUMBER

3738

DATE MAILED: 12/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

VP

Office Action Summary	Application No.	Applicant(s)	
	09/940,722	SCHACHAR, RONALD A.	
	Examiner	Art Unit	
	Dave Willse	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 61-106 is/are pending in the application.
- 4a) Of the above claim(s) 71-73, 91-93 and 104-106 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 61-70, 74-90, and 94-103 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 61-68, 70, 74-88, 90, 94-101, and 103 are rejected under 35 U.S.C. 102(b) as being anticipated by Schachar, US 5,354,331. Regarding claim 1 and others, Schachar '331 discloses an ocular scleral prosthesis in the form of an adjustable scleral expansion band (column 7, lines 1-4) comprising at least one elongated body in the form of a strip of material (column 7, lines 4-8) capable of being implanted in a corresponding elongated pocket within scleral tissue of an eye in the zone exterior to the ciliary body (column 7, lines 36-39). Inner and outer surfaces of said flap are capable of contacting the base and the flap of the scleral pocket (column 7, lines 39-42; drawings) and are separated by enough distance or thickness to impart sufficient structural characteristics (e.g., strength) to elevate the flap and exert outwardly directed traction on at least the anterior margin of the pocket (column 7, lines 8-12; column 5, lines 38-41; etc.). Regarding the language newly added to claim 1, the Schachar '331 adjustable band is structured to be positioned in the region of the ciliary body and thus generally coincides with a "small circle" rather than a "great circle" of the eye globe (as illustrated in the Applicant's own Figure 4, for example). According to the *Wikipedia* online encyclopedia (accessible through

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onelook.com), “[a] **great circle** is a circle on the surface of a sphere that has the same circumference as the sphere, dividing the sphere into two equal hemispheres”, and “[a] **small circle** of a sphere is the circle constructed by a plane crossing the sphere not in its center”; “[s]mall circles always have smaller diameters than the sphere itself (compare great circle)”. The pocket length of Schachar ‘331 is further lessened a small but definite amount by virtue of the scleral tissue thickness overlying the pocket.

In regard to claim 61, the expression “more distal” is not defined in a manner prescribed in MPEP § 2111.01, so the term is given its broadest reasonable interpretation (MPEP § 2111). Along the circumferential dimension (and extent) of each elongated part of the scleral band (column 7, lines 1-3), one end is situated farther away than any other portion of the part from the other end. Additionally, the alternative scleral alloplant strip (column 8, lines 22-26) clearly meets the newly added limitations, with the “means for expanding” (instant claim 61, last two lines), being equated with the weakening and engrafting of the sclera (column 8, lines 3-4, 12-19, and 22-23). Regarding claim 74, “a distance” can be interpreted similarly to “distal” as explained above, because each elongated part defines a length or distance along a curve. Regarding claim 62, the ridge or crest limitation is met by the thread of the screw mechanism (column 7, lines 8-12), which is a means for expanding the contacted sclera to increase the effective working distance of the ciliary muscle (column 7, lines 8-12; column 2, lines 67-68; etc.). Regarding claim 88, the *helical* ridge or thread extends along *both* dimensions of the strip planform. Regarding claim 94, the tangential screw mechanism (involving a ridge member or thread) on the base member or strip of material applies a force to the scleral pocket via the strip of material.

Claims 61-70, 74-79, 89, and 102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schachar, US 5,354,331. Regarding claims 61 and 74, the “plurality of parts” (column 7, line 2) being greater than two parts so that each part subtends an angle of less than 180° (and thereby clearly meets the newly added limitations pertaining to “more distal” and greater “distance”) would have been obvious, if not inherent, from the use of the word “plurality” rather than “pair” and from the innate goal of providing various options to the surgeon, with further motivation having been provided by the contemplated removal of the band (column 8, lines 52-58): an arc-shaped part or component would require less complicated excision techniques than a one or two piece annular implant. Regarding claims 69, 89, and 102, the particular dimensions for each of the “plurality of parts” (column 7, line 2) would have been obvious from anatomical considerations.

The Applicant’s remarks have been considered. The Applicant alleges that “[t]he Office action cites no evidence supporting an interpretation of the term ‘ridge’ that would encompass a screw or threads” (page 15, lines 10-11, of the reply filed on September 26, 2006). A “ridge” is defined as “an elevated body part (as along the backbone)” (*Merriam Webster’s Collegiate Dictionary*, 10th edition: 1996); a thread is elevated with respect to the root of the screw. Other issues are adequately addressed in the grounds of rejection presented above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse whose telephone number is 571-272-4762 and who is generally available Monday through Thursday and often on Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Dave Willse
Primary Examiner
Art Unit 3738